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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,934	02/15/2002	Richard M. O'Hara JR.	WYS-00701	3689
58571 7590 01/24/2008 FOLEY HOAG, LLP/WYETH PATENT GROUP, (w/WYS) 155 SEAPORT BLVD. BOSTON, MA 02210-2600			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/076,934

Applicant(s)

O'HARA ET AL.

Examiner

ILIA OUSPENSKI, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-12 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-12, 28, 30 and 32-36 is/are rejected.
- 7) ☒ Claim(s) 29, 31 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/31/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 10/31/2007 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claims 5 – 8 and 13 – 27 have been canceled.

Claims 1 – 4, 9 – 12, and 28 – 37 are pending.

This Office Action is in response to Applicant's amendment and arguments, filed on 10/31/2007.

The rejections of record can be found in the previous Office Action, mailed on 03/08/2007.

The rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

It is noted that New Grounds of Rejection are set forth herein.

2. The disclosure is objected to for failing to comply with 37 CFR 1.821(d), because the sequences disclosed at least on page 30, lines 9 and 10, *are not accompanied by SEQ ID Numbers*.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in response to this Office Action.

3. The following is a quotation of **35 U.S.C. 103(a)** which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 4, 9 – 12, 28, 30, and 32 – 36 are rejected under 35 U.S.C. **103(a)** as being obvious over Linsley et al. (US Pat. No. 5,521,288; of record, see entire document), or, in the alternative, over Yu et al. (US Pat. Pub. No. 2002/0006403; of record; see entire document).

Both Linsley et al. and Yu et al. have been discussed in detail in previous office actions, and teach methods of treating autoimmune diseases, including type I diabetes, by administering anti-CD28 antibodies (specific references provided in the previous office actions).

Applicant argues that the references are not enabled for treating diabetes in a patient, because the working examples are allegedly limited to in vitro experiments.

In response, Applicant's attention is drawn to Example 3 (page 22) of Yu et al., where the reference provides evidence that anti-CD28 antibody is effective in downmodulating an immune response in vivo.

Furthermore, even assuming, *arguendo*, that the cited references were not enabling at the time the instant invention was made, it would have been obvious to a person of ordinary skill in the art to try treating type I diabetes with blocking anti-CD28 antibodies, for the following reasons:

It was well known in the art at the time the invention was made that CD28 is a costimulatory receptor, whose activation by B7-1 and B7-2 ligands contributes to upmodulation of an immune response both in vitro and in vivo. Therefore, one of skill in the art would understand that blocking interaction of B7-1 and/or B7-2 with CD28, such as by an anti-CD28 antibody, would result in downmodulation of an immune response. The skilled artisan was further aware of the desirability of downmodulating immune responses in autoimmune diseases, such as type I diabetes, as evidenced by both

Linsley et al. and Yu et al. The skilled artisan had a reasonable expectation of success, at least in view of the in vivo data of Yu et al. The scFv technology and its advantages were well known at the time the invention was made, as evidenced by the references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. Conclusion: claims 29, 31, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI, Ph.D. whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, reading "Ilia Ouspenski". The signature is written in a cursive style with a large, looping initial "I".

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644

January 21, 2008